



Consumer Group Asks FDA to Seize Synthetic Ephedrine "Supplements"

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WASHINGTON--Ralph Nader's consumer group asked the Food and Drug Administration (FDA) to seize products labeled as dietary supplements that contain a synthetic form of ephedrine. Public Citizen (www.publiccitizen.org) sent a letter to Tommy Thompson, Secretary of Health and Human Services, regarding 10 products containing synthetic ephedrine being marketed on the Internet by nine manufacturers as dietary supplements.

The letter asks FDA to seize the products as unapproved new drugs because they contain synthetic ephedrine alkaloids. FDA has taken action against these types of products before, most recently against E'Ola International. (For more on that story, see <http://www.naturalproductsinsider.com/articles/1c1govn4.html>.)

In the letter to Thompson, the group noted, "The inclusion of synthetic compounds in dietary supplements is expressly prohibited by the Food, Drug and Cosmetic Act, which limits supplement ingredients to those that are concentrates, metabolites, constituents or extracts of dietary substances." It also referenced a letter sent to Rep. Henry Waxman (D-Calif.) from Melinda Plasier, FDA's associate commissioner for legislation, that "FDA has further concluded that products containing synthetic ephedrine alkaloids do not fall under the dietary

supplement regulatory scheme and should be regulated as drugs."

After the December E'Ola seizure, the American Herbal Products Association (AHPA) issued a reminder that "AHPA's long-standing ephedra trade recommendation prohibits the use of any synthetically derived ephedrine alkaloids in any dietary supplement product."

This echoes the position of other dietary supplement industry associations. Diane McEnroe, legal counsel for the National Nutritional Foods Association (NNFA), noted that NNFA's ephedra guidance focuses on the use of natural source ephedra from ma huang. The guidance outlines industry standards for the formulation, labeling and marketing of dietary supplements containing ephedrine alkaloids. It notes: "Neither finished consumer goods nor raw materials used in their manufacture are to contain any synthetically derived ephedrine alkaloids or their salts (e.g., ephedrine sulfate; pseudoephedrine hydrochloride; phenylpropanolamine hydrochloride)."

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